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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
BRASSICA PROTECTION PRODUCTS LLC, and:
THE JOHNS HOPKINS UNIVERSITY

1:07-cv-07844-SAS

Plaintiffs, :

-against- :

CAUDILL SEED & WAREHOUSE CO., INC. :

Defendant. :

-----X

**CAUDILL SEED &
WAREHOUSE CO., INC.'S
CLAIM CONSTRUCTION
BRIEF**

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I. INTRODUCTION

Defendant Caudill Seed & Warehouse Co., Inc. (hereinafter “Caudill”) submits its initial brief in support of its proposed claim construction for the patents asserted against it by Plaintiff The Johns Hopkins University (hereinafter “JHU”), and its licensee, Plaintiff Brassica Protection Products LLC (hereinafter “BPP”), (collectively, hereinafter, “Plaintiffs”).

At issue are 19 disputed terms from U.S. Patent Nos. 5,725,895 (“the ‘895 patent”) a copy of which is attached as Exh. 1-A; 5,968,567 (“the ‘567 patent”) Exh. 2-A; 6,177,122 (“the ‘122 patent”) Exh. 3-A; 6,242,018 (“the ‘018 patent”) Exh. 4-A and 7,303,770 (“the ‘770 patent”) Exh. 5-A (for purposes of this brief, “the patents-in-suit”). However, there are three concepts that largely govern the disputed terms: (1) what is a food product; (2) what is an extracting process and what is an extract; and (3) what does crucifer and cruciferous mean in the context of the patents-in-suit. The answers are apparent: (1) food product has been clearly defined in the “Definitions” section of the patents-in-suit by the patentees, (2) the definitions of extracting and extract are clear in view of the specification and supporting extrinsic evidence, which shows the ordinary and customary meaning of the terms to those skilled in the art at the time of the invention, and (3) crucifer and cruciferous are defined in the patents and their prosecution histories. Regarding the remainder of the disputed terms, the proposed constructions are provided in the claim chart below.

II. BACKGROUND

A. Patents-in-Suit

The patents-in-suit are related to one another because they are either a divisional or a continuation of a prior or first-filed application. Because they are all related, they have an identical specification. *Manual of Patent Examining Procedure* §§ 201.06, 201.07.

Furthermore, the patent examiner found the claims of the five patents to be so closely related that they were deemed to be patentably indistinct from one another. All patents, except for the initial '895 patent, are subject to a terminal disclaimer so they will all expire when the '895 patent expires. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1318-19 (Fed. Cir. 2007) (“The purpose of the terminal disclaimer is to prevent extension of the patent term for subject matter that would have been obvious over an earlier filed patent.”); 35 U.S.C. § 253. Because each of the patents-in-suit has the same specification, all references in this memorandum will be to the '895 patent specification.

The first-filed application that became the '895 patent was filed on September 15, 1995. Exh. 1-A. The '567 patent claims priority from, and is a continuation of, the '895 patent. Exh. 2-A. The '122 patent is a divisional of, and so claims priority from, the '567 patent and the '895 patents. Exh. 3-A. Similarly, the '018 patent is a divisional of, and so claims priority from, the '122 patent, which is itself identified on the face of the '018 patent as a divisional of the '567 patent. Exh. 4-A. Finally, the '770 patent is a divisional of the '018 patent, which is identified on the face of the '770 patent as a divisional of the '122 patent, which is identified as a divisional of the '567 patent. Exh. 5-A.

Plaintiffs allege that Caudill infringes only certain claims of the patents-in-suit, which are identified in the parties' joint Claim Construction Statement (“the asserted claims”). Relying on those contentions, Caudill has limited its identified claim construction issues to those raised by the asserted claims. It reserves the right to amend its claim constructions in the event that Plaintiffs assert additional claims against Caudill. Further, although Caudill seeks a declaration of invalidity and noninfringement of all the claims of the patents-in-suit, plus three additional

patents owned and licensed by Plaintiffs, the additional patents have terminology in common with the claim terms discussed in this Memorandum.

B. Technology

The patents-in-suit are directed to chemical components found in common vegetables, known as crucifers, to form food products, and a method of preparing the food products. According to the patent specifications, the chemical components are “glucosinolates” and “isothiocyanates” (hereinafter “G&I”) and the crucifers include broccoli and cauliflower. See Exh. 1-A at col. 10, ll. 32-65.

According to the patents-in-suit, G&I were known to be present in certain crucifers and to have anti-cancer properties. *Id.* at col. 1, ll. 28-29, 48-51, 54-62; col. 2, ll. 8-12, 19-20; col. 8, ll. 16-18. Prior art methods existed and were used to isolate G&I, and to evaluate their anti-carcinogenic properties. *Id.* at col. 2, ll. 8-18. G&I have been found in many different families of edible plants, and the amount of G&I present depends upon family, genus, species, variety, or cultivar of the plant selection and on growth and harvesting conditions. *Id.* at col. 2, ll. 19-24. The patent also states that strategies for the crossing, selection and breeding of new cultivars of Cruciferae were well known to the skilled artisan in this field, *Id.* at col. 12, ll. 11-13, and disclosed a prior art method for extraction of G&I from vegetables by homogenizing the vegetables in cold water, freeze-drying them, and removing the resulting powder with a solvent. *Id.* at col. 8, ll. 28-33.

The patent specification states that there is a need to identify particular edible plants and a method of growing and preparing them to yield high levels of Phase 2 enzyme inducer activity for chemoprotection. *Id.* at col. 2, ll. 23-27. However, it is clear that Plaintiffs did not invent new vegetables: the list of “suitable” crucifers contains only well-known, common varieties of

broccoli and cauliflower, *Id.* at col. 10, ll. 27 – col. 11, l. 17, which they identified using known factors (family, genus, species, variety, cultivar of the plant selection, and growth and harvesting conditions), and they admit that breeding new cultivars is well known in the art. *Id.* at col. 2, ll. 19-23. It is further clear that Plaintiffs did not invent new uses for G&I – their health benefits were well-documented. *Id.* at col. 1, ll. 28-29, 54-58; col. 8, ll. 14-16. Nor did they invent a method to remove G&I from vegetables as the patent discloses methods well known in the art at the time the first patent application was filed. *Id.* at col. 11, ll. 60-65. Rather, the patents-in-suit purport to cover an “improved” method “to improve upon the previously described techniques for homogenization and extraction of those vegetables.” *Id.* at col. 8, ll. 25-28.

III. CLAIM CONSTRUCTION STANDARD

A. The Scope of Protection of the Patents-in-Suit

The legal protection afforded by each of the patents-in-suit is defined by its “claims.” That is, the claims of a patent define the “invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The claims are the numbered paragraphs that appear at the end of the patent.

The patent claims are required to particularly point out and distinctly claim the subject matter which the applicant regards as his invention and defines the scope of the patent grant. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996)(citations omitted); 35 U.S.C. § 112. The purpose of requiring clear patent claims is to notify the public of the metes and bounds of the “invention” so that competitors can ascertain with reasonable certainty the scope of the patentee’s right to exclude. *See, e.g., Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1023 (Fed. Cir. 1998) (J. Michel, additional views) (“As the Supreme Court reemphasized ... the notice function of patents is critical ... Market participants as well as judges and jurors

must be able to ascertain what subject matter is covered by the right to exclude.”) (citations omitted).

B. The Law of Claim Construction

The words of a claim “are generally given their ordinary and customary meaning,” unless it appears that the inventor used them differently. *Phillips*, 415 F.3d at 1312.; *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951 (Fed. Cir. 1993) (citations omitted). “[The Federal Circuit has] made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. For claim construction purposes in this case, the effective filing date of the first patent application was September 15, 1995 (see first page of the ‘895 patent, Exh. 1-A).

The person of ordinary skill in the art is deemed to read the claim term in the context in which a claim term is used in the intrinsic record - the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1313. In some cases, the ordinary meaning of a claim term may be readily apparent, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. *Id.* at 1314.

The claims themselves can provide substantial guidance as to the meaning of particular claim terms. *Id.* Consideration of the other claims of the patent, both asserted and unasserted, by the court can be highly instructive. *Id.* For example, since claim terms are normally used consistently throughout a patent, the usage of a term in one claim may illuminate the meaning of the same term in other claims. *Id.* Also, differences between claims may be a guide in understanding the meaning of particular claim terms. *Id.*

The patent claims do not stand alone however; the proper meaning of claim terms is necessarily informed by the patent's specification. *Id.* at 1315. "The specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is *the single best* guide to the meaning of a disputed term." *Id.* at 1315 (emphasis added). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* at 1321.

The Federal Circuit has also stated that the specification may serve to limit claim scope where: (1) the specification expressly defines the term used in the claim or defines it by implication, *Id.* at 1321, (2) the specification limited the invention to embodiments with a particular feature, *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000), and (3) the embodiment is described as being the invention itself, *e.g.*, statements in the "summary of the invention" describing the overall invention, *see, e.g., Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1347-48 (Fed. Cir. 2004); *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 860-61 (Fed. Cir. 2004).

The Federal Circuit has made it clear that in construing patent claims, "a court 'should also consider the patent's prosecution history.'" *Phillips*, 415 F.3d at 1317 (*quoting Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995)). "The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 957 (Fed. Cir. 2000). It may show "whether the patentee disclaimed or disavowed subject matter, [thereby] narrowing the scope of the claim terms." *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1091 (Fed. Cir.

2003)(citations omitted). For example, where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language. *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002)(“Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations.”); *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997)(“[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection.”). In addition, statements made in the prosecution of one patent are relevant to the scope of all related patents. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (citations omitted). The prosecution histories of the patents-in-suit are included in the parties’ Joint Exhibits.

Although less significant than intrinsic evidence in claim construction, courts may in certain circumstances rely on extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317. However, such evidence must be relevant to “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Id.* at 1318. Since the effective filing date of the patents-in-suit was September 15, 1995, to look at how any of the claim terms in dispute were used after that date is simply irrelevant to the claim construction issues to be decided by this Court. Further, such extrinsic evidence must be sufficiently public that it would have been known by a person of ordinary skill in the art at the time the patent application was filed.

Extrinsic evidence, such as expert testimony, can be used *only* where there is some

genuine ambiguity in the claims after consideration of all available intrinsic evidence. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996); *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000) (“The court turns to extrinsic evidence only when the intrinsic evidence is insufficient to establish the clear meaning of the asserted claim.”)(citations omitted). “[E]xtrinsic evidence in general, and expert testimony in particular, may be used to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language.” *Vitronics*, 90 F.3d at 1584. That is, “while a trial court may use extrinsic evidence to educate itself about the invention and the relevant technology, it may not use extrinsic evidence to arrive at a claim construction that is at odds with the intrinsic evidence.” *Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 908 (Fed. Cir. 2005).

In the end, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be ... the correct construction.” *Phillips*, 415 F.3d at 1316 (*quoting Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

IV. ARGUMENT

A. A Person Of Ordinary Skill In The Art

As noted above, claim terms are to be given the meaning that they would have to a person of ordinary skill in the art at the time of the invention. *Phillips*, 415 F.3d at 1312 (citations omitted). The “hypothetical ‘person having ordinary skill in the art’ to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art.” *Ex parte Hiyamizu*, 10 U.S.P.Q.2d (BNA) 1393, 1394 (Bd. Pat. App. & Interferences Apr. 28, 1988). The patent is drawn to food products

and methods of making food products. Based on the subject matter of the patent, a person of ordinary skill in the art at the time of the invention, who is capable of understanding the scientific and engineering principles applicable to the pertinent art, has been defined by Caudill's expert, Dr. Gregory Ziegler, as follows:

In my opinion, one of "ordinary skill in the art" would have at least a B.S. degree in Chemical, Food or Agricultural Engineering, Analytical Chemistry, or academic courses in process engineering specifically in unit operations in chemical engineering and separation processes including leaching.

Rebuttal to opinion of Edward M. Sybert, dated March 20, 2008 at 2, Exh. 10-A.

B. Proposed Constructions for Primary Claim Terms

1. Food Product

"Food product" means any ingestible preparation containing the sprouts of the instant invention, which are identified and have the characteristics described in the '895 patent specification, at col. 10, l. 28 - col. 11, l. 17, or extracts or preparations made from these sprouts, which are capable of delivering Phase 2 inducers to the mammal ingesting the food product.

a. The Patent Specification Expressly Defines "Food Product"

Under the heading "Definitions," the patent states: "In the description that follows, a number of terms are used extensively. The following definitions are provided to facilitate understanding of the invention." Exh. 1-A at col. 6, ll. 12-14 (emphasis added). Under the definitions section, "food product" is expressly defined as follows:

A food product is any ingestible preparation containing the sprouts of the instant invention, or extracts or preparations made from these sprouts, which are capable of delivering Phase 2 inducers to the mammal ingesting the food product. The food product can be freshly prepared such as salads, drinks or sandwiches containing sprouts of the instant invention. Alternatively, the food product containing sprouts of the instant invention can be dried, cooked, boiled, lyophilized or baked. Breads, teas, soups, cereals, pills and tablets, are among the vast number of different food products contemplated.

Id. at col. 6, ll. 26-37 (emphasis added).

According to the Court of Appeals for the Federal Circuit, the Court has “repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification.” *Sinorgchem Co., Shandong v. Int’l Trade Comm’n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007). A “patentee must be bound by the express definition” he provides when “the drafter clearly, deliberately, and precisely define[s] the term.” *Id.* (citations omitted); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (“[A] claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in ... the specification ...”); *Vitronics*, 90 F.3d at 1582 (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”).

In *Sinorgchem*, the patentee clearly, deliberately and with precise language defined a particular claim term. *Sinorgchem*, 511 F.3d at 1136. At trial, the patentee argued that a portion of that definition should not be considered because it was merely an example and that it would render some of the disclosed embodiments inoperable. *Id.* at 1137. The Court found the definition to be complete and without ambiguity so that it no longer needed to search for the term’s meaning. *Id.* at 1138. Further, the Court noted that the word ‘is,’ a term used here in the specification of the patents-in-suit, may ‘signify that a patentee is serving as its own lexicographer.’ *Id.* at 1136 (*quoting Abbott Labs v. Andrx. Pharms.*, 474 F.3d 1196, 1210 (Fed. Cir. 2007)).

In this case, the specification reveals “a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.” *Phillips*, 415 F.3d at 1316. Because these statements are directed to the invention as a whole, and not just a particular embodiment, they serve to limit the sprouts in the food product to those identified and described

in the patent itself. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1367 (Fed. Cir. 2007). The patent statements make particularly clear that “food product” must include sprouts “of the instant invention.”

b. The Prosecution History Reinforces That “Food Products” Must Contain Sprouts

During the prosecution of the ‘895 patent and its related patents, the patent applicants emphasized that “food products” must include sprouts of the instant invention. The applicants argued repeatedly that their claims were patentable over the prior art because they provided “food products” or “human food products” that comprised the particular cruciferous sprouts or sprout extracts identified in the patents. As a result of those argument, those terms are limited to food products that contain sprouts or sprout extracts - the sprouts identified and exhibiting the characteristics described at col. 10, l. 28 – col. 11, l. 17 of Exh. 1-A. *Seachange Int’l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005) (“Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of otherwise broad claim language.”).

For example, during the prosecution of the ‘895 patent, the applicants distinguished the claims over the cited prior art by the following statements:

“Beecher therefore does not teach or suggest methods for the production of food products comprised of the recited cruciferous sprouts or sprout extracts.” Amendment, dated March 17, 1997, at 3 (emphasis added). Exh. 1-C at 38.

“However, the [prior art]’94056 application fails to teach the claimed methods for preparing food products comprised of the recited cruciferous **sprouts** or **sprout** extracts.” *Id.* (emphasis in original).

“The ‘94056 application does not describe a method for preparing broccoli **sprouts**.” *Id.* at 4 (emphasis in original). Exh. 1-C at 39.

“The prior art does not teach or suggest methods for production of food products comprised of the recited cruciferous sprouts or sprout extracts.” *Id.* at 8 (emphasis added). Exh. 1-C at 43.

In support of those arguments, applicants submitted a declaration of one of the inventors, Dr. Paul Talalay. Dr. Talalay agreed that, as used in the patent claims, a “food product” required sprouts:

“None of the prior art references cited by the examiner in the Official Action, either alone, or in combination, teach or suggest the claimed methods for preparing food products comprised of the designated cruciferous sprouts, or extracts made from these sprouts.” Declaration of Paul Talalay, dated March 13, 1997, at ¶5 (emphasis added). Exh. 1-D at 12.

“The methods of the application also provide food products comprised of certain cruciferous sprouts and sprout extracts...” *Id.* at ¶11 (emphasis added). Exh. 1-D at 15.

The examiner clearly understood that “food product” must include the particular sprouts identified in the patent specification because, in her reason for allowing the application that became the ‘895 patent, she stated:

The following is an examiner’s statement of reasons for allowance: a method of preparing a food product wherein cruciferous sprouts, with the exception of cabbage, cress, mustard, and radish sprouts are harvested prior to the 2-leaf stage is not taught nor fairly suggested by the prior art or any combination thereof.

‘895 patent Notice of Allowability, dated August 14, 1997, at 3. Exh. 1-D at 32.

Similar limiting arguments were made during the prosecution of the ‘567 patent. The examiner summarized an interview with the applicants by stating “[a]pplicants’ method is directed to sprouts containing high Phase 2 enzyme-inducing potential and non-toxic levels of indole glucosinolates and their breakdown products.” Interview Summary, dated June 19, 1998 (emphasis added). Exh. 2-D at 18.

In an Amendment and Request for Reconsideration, dated June 30, 1998, the applicants again distinguished their claimed “food products” over the prior art because the claimed “food products” contained sprouts or sprout extracts:

“None of the prior art references cited by the examiner in the Official Action, either alone, or in combination, teach or suggest the claimed methods for preparing food products comprised of the designated cruciferous sprouts, or extracts made from these sprouts.” Amendment, dated June 30, 1998, at 3 (emphasis added). Exh 2-D at 28.

“Mr. Meyerowitz does not teach that the claimed sprouts are well known. The teaching of Meyerowitz does not even indicate that the claimed sprouts have been made.” *Id.* (emphasis added).

“This important error demonstrates that Mr. Meyerowitz was simply speculating about the anti-cancer potential of these vegetables and could not have known that the food product comprised of cruciferous sprouts produced by the claimed method has advantageous properties revealed by the inventors of the instant application.” *Id.*

“Beecher therefore does not teach or suggest methods for the production of food products comprised of the recited cruciferous sprouts or sprout extracts.” *Id.* at 4 (emphasis). Exh 2-D at 29.

“Likewise, the two Zhang articles and the Cho patent fail to teach or suggest methods for the production of food products comprised of the recited cruciferous sprouts or sprout extracts” *Id.* (emphasis added).

“More specifically, the claimed methods of the instant application provide food products comprised of certain cruciferous sprouts, and sprout extracts.... As a consequence, a significant health benefit can be realized through ingestion of small quantities of cruciferous sprouts, or sprout extracts, prepared according to the claimed methods.” *Id.* at 5 (emphasis added). Exh 2-D at 30.

“Another unrecognized and unexpected benefit of the claimed methods is to provide food products comprised of certain cruciferous sprouts and sprout extracts . . .” *Id.* at 7 (emphasis added). Exh 2-D at 32.

“The prior art does not teach or suggest methods for production of human food products comprised of the recited cruciferous sprouts or sprout extracts.... The claimed methods of the instant application provide food products comprised of certain cruciferous sprouts, and sprout extracts....” *Id.* at 8 (emphasis added). Exh 2-D at 33.

In support of these arguments, Dr. Talalay provided another declaration in which he stated:

“None of the prior art references cited by the examiner in the Official Action, either alone, or in combination, teach or suggest the claimed methods for preparing food products comprised of the designated cruciferous sprouts, or extracts made from these sprouts.” Declaration of Paul Talalay, dated June 18, 1998, at ¶5 (emphasis added). Exh. 2-E at 29.

The claimed methods of the application provide food products that not only contain unexpectedly high levels of anticarcinogenic Phase 2 inducer activity, but also contain unexpectedly low levels of potentially carcinogenic Phase 1 enzyme inducer activity. The prior art references relied on by the examiner do not teach or suggest these unexpected attributes of the human food product made by the claimed methods. The sprouts and their extracts are therefore both qualitatively and quantitatively radically different in their content of enzyme inducer activities compared to mature, market stage vegetables. *Id.*, ¶7 (emphasis in original). Exh. 2-E at 30.

“The methods of the application also provide food products comprised of certain cruciferous sprouts and sprout extracts....” *Id.*, at ¶12 (emphasis added). Exh. 2-E at 33.

In the prosecution of related patent, U.S. Patent No. 5,968,505, the applicants still argued that the term “food product” must include sprouts or sprout extracts:

“More specifically, the claimed methods of the instant application provide food products comprised of certain cruciferous sprouts, and sprout extracts....” Amendment, dated January 25, 1999, at 4 (emphasis added). Exh. 6-D at CSC017646.

“Another unrecognized and unexpected benefit of the claimed methods is to provide food products comprised of certain cruciferous sprouts and sprout extracts....” *Id.*, at 6-7 (emphasis added). Exh. 6-D at CSC017648-49.

“The claimed method of the instant application provides food products comprised of certain cruciferous sprouts, and sprout extracts....” *Id.*, at 8 (emphasis added). Exh. 6-D at CSC017650.

This amendment referenced yet another declaration by Dr. Talalay in which he states again that “[t]he methods of the application also provide food products comprised of certain cruciferous sprouts and sprout extracts....” Declaration dated February 18, 1999, at ¶12 (emphasis added). Exh. 6-D at CSC017656.

Such numerous and unequivocal statements requiring food products to include sprouts made over several applications not just by the attorney prosecuting the application but several times by one of the named inventors himself is a “clear and unmistakable” limiting of a claim term. *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) (“a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.”) (citations omitted).

Nothing was said by the applicants during the prosecutions of the rest of the patents-in-suit that would contradict the express definition provided in the specification for the term “food product” or its related term “human food product,” or the clear affirmation of that definition in the preceding prosecutions of all of the related patents.

Given that the applicants argued repeatedly that their claims were patentable over the prior art because they provided “food products” or “human food products” that comprised “designated” or “recited” cruciferous sprouts or sprout extracts, those terms are limited to food products that contain the specific sprouts or sprout extracts recited in Exh. 1-A, col. 10, l. 28 – col. 11, l. 17. *See Seachange*, 413 F.3d at 1373 (“[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, [and] he is by implication surrendering such protection.”) (quotations omitted).

The fact that “food product” and “human food product” are in the preambles of the claims does not save Plaintiffs from this narrowing construction. Throughout the prosecution of this entire family of patents, the applicants have defined the term “food product” to distinguish over the prior art, and thus, narrow its meaning. In such a case as this, where the preamble gives “life, meaning, and vitality to the claim,” it is properly a limitation of the claim. *Catalina Mktg. Int’l, Inv. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002).

2. Extracting ... from, Extracted, and Extract.

The verb “extracting ... from” means the process of removing glucosinolates and isothiocyanates by a solvent from solid material, *i.e.*, seeds, sprouts, etc.

The noun “extract” means “material removed from a solid by use of a solvent, wherein the extract can contain the removed material and the solvent.” In other words, the extract contains solvent and G&I.

The adjective “extracted” has two meanings, depending on its context. When it is used to describe the “extracted glucosinolates and isothiocyanates” it means the G&I that have been removed from the seeds, sprouts, etc. by an extraction process. When it is used to describe the “extracted sprouts, seeds, or combinations thereof” it means the sprouts, etc. that have had G&I removed via an extraction process.

“Claim terms are entitled to a heavy presumption that they carry their ordinary and customary meaning to those skilled in the art in light of the claim term’s usage in the patent specification.” *Elbex Video Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (citations omitted). A person of ordinary skill in the art is “deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field.” *Phillips*, 415 F.3d at 1313 (*quoting Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When construing the claim terms containing “extracting ... from,” “extracted,” and “extract,” resort may be had to sources including “the words of the claims themselves, the remainder of the specification, the prosecution history, extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Phillips*, 415 F.3d at 1314.

a. The Context of the Claims

In the context of the claims, “extracting ... from” is used as a verb always in the context of extracting G&I from seeds, sprouts, plants, plant parts, or a combination thereof. “The context of the surrounding words of the claim must also be considered in determining the ordinary and customary meaning of those terms.” *Walt Disney*, 346 F.3d at 1088. From the

plain meaning of the context of the term “extracting ... from,” it is clear that the G&I are removed from the seeds, etc.

This is the same meaning the verb “extracting ... from” would have had to a person of ordinary skill in the art at the time the ‘895 patent application was filed. As explained by Dr. Ziegler, in his Expert Opinion dated March 10, 2008, Exh. 8, and his Rebuttal Opinion dated March 20, 2008, Exh. 10-A, persons of ordinary skill in the art (as defined above in Section III.B.) at the time of the filing of the application would look to chemistry and engineering texts for a definition of the term. At the time of the patent filing, such a person would have found the definitions proposed by Caudill. For example, a well-known and widely used engineering text of the time explained:

A process in which a liquid solvent is used to remove a desired compound (or compounds) from insoluble material is termed leaching or solid extraction. In such a process, the extract is the material removed from the insoluble solids by the solvent, and may or may not be additionally separated, *i.e.*, recovered, from the solvent. The material from which the extract is obtained is referred to as the raffinate, spent solids, residue or pulp.

W.L. McCabe, et al., UNIT OPERATIONS OF CHEMICAL ENGINEERING 533 (4th ed. McGraw-Hill Book Co. 1985) (emphasis added). Exh. BB at B002018.

The same definitions are employed in the related process of liquid-liquid extraction:

In all such operations, the solution which is to be extracted is called the feed, and the liquid with which it is contacted is the solvent. The solvent-rich product of the operation is called the extract, and the residual liquid from which the solvent has been removed is the raffinate (Treybal, 1980 at 477). Exh. CC at CSC023326.

Jamie Benitez, PRINCIPLES AND MODERN APPLICATIONS OF MASS TRANSFER OPERATIONS 385 (John Wiley & Sons, Inc. 2002). Exh. DD at B002053.

“Extraction may refer to a solute being removed from either a solid or a liquid.”

L. Erickson, *Extraction System Design*, in Encyclopedia of Agricultural, Food and Biological

Engineering 290 (Dennis Heldman ed., Marcel Dekker Inc. 2003). Exh. 10-B at CSC019412.

Examples given in this text include: caffeine extracted from coffee beans, oils extracted from soybeans, vanilla extracted from vanilla beans, and enzymes extracted from cell homogenates.

Id.

Many naturally occurring organic products are separated from their original structure by leaching. For example, sugar is leached from sugar beets with hot water, vegetable oils are recovered from seeds such as soybeans and cottonseed by leaching with organic solvents, tannin is dissolved out of various tree barks by leaching with water, and many pharmaceutical products are similarly recovered from plant roots and leaves. Tea and coffee are prepared both domestically and industrially by leaching operations.

Robert E. Treybal, Mass-Transfer Operations 477, 717-19 (3d ed. McGraw-Hill Book Company 1980). Exh. CC at CSC023323-26.

Numerous other examples of technical treatises containing the definitions of “extracting ... from,” “extracted,” and “extract” are provided in Caudill’s Claim Construction Chart, attached hereto as Exh. AA.

This same usage is seen in other publications dated about the time of the ‘895 patent application filing:

An article published by Dr. Ziegler describes extraction of free fatty acids, off-odors or flavors from edible fats and oils. Carbon dioxide is the solvent, the solvent plus free fatty acids, off-odors and flavors is described as the extract, and the cleansed edible fats and oils are referred to as the raffinate. The free fatty acids in the extract are then “recovered.” G.R. Ziegler & Y.J. Liaw, *Deodorization and Deacidification of Edible Oils Using Dense Carbon Dioxide*, 70 J. Am. Oil. Chem. Soc. 947-953 (1993). Exh. EE.

Two patents on which Plaintiff’s expert, Mr. Edward M. Sybert, is identified as an inventor describe “extracting” sugars “from” citrus solids using hot water. The water/sugar mixture is described as an “extract.” After this process is completed, the citrus solids are

referred to as “extracted shard residues.” Particular compounds are described as being further “recovered” from the water/sugar extract. Milch et al., “Preparation of High Fructose Syrups from Citrus Residues,” U.S. Patent 4,488,912, December 18, 1984, Exh. FF; Milch et al., “Preparation of High Fructose Syrups from Citrus Residues,” U.S. Patent 4,547,226, October 15, 1985. Exh. GG.

Based on the above information, a person of ordinary skill in the art would conclude that the verb “extracting ... from” means the process of removing G&I by a solvent from solid material, *i.e.*, seeds, sprouts, etc. This is the same process one uses to make a cup of tea: one puts the tea leaves (the solid material) into hot water (the solvent) to make brewed tea (the extract which contains the tea flavor).

Likewise, it is clear that in the context of the claims the noun “extract” means material removed from a solid by use of a solvent, wherein the extract can contain the removed material and the solvent. In other words, the extract contains solvent and G&I.

The adjective “extracted” has two meanings, depending on its context. When it is used to describe the “extracted glucosinolates and isothiocyanates” it means the glucosinolates and isothiocyanates (“G&I”) that have been removed from the seeds, sprouts, etc. by an extraction process. Continuing the tea analogy, the “extracted” G&I is the same as the brewed tea which contains the extracted flavors and color. When “extracted” is used to describe the “extracted sprouts, seeds, or combinations thereof” it is referring to the sprouts, etc. that have had G&I removed via an extraction process. In the tea example, the “extracted” sprouts, etc. are the same as the used tea bag. Although generally there is a presumption that a claim term will have the same meaning throughout a patent, that presumption can be overcome when the different meanings are clear from the context of the claims. *Phillips*, 415 F.3d at 1314 (claims are

construed according to one of ordinary skill in the art at the time of the invention in the context the term is used). In this case, the dual usage is common in the art and can be easily understood in the context of the claims.

b. The Patent Specification

The patent applicants used “extracting ... from,” “extracted” (in both its contexts), and “extract” in the patent specification consistent with its ordinary meaning:

Non-toxic solvent extracts according to the invention are useful as healthful infusions or soups. Non-toxic or easily removable solvents useful for extraction according to the present invention include water, liquid carbon dioxide or ethanol, among others. The sprouts can be extracted with cold, warm, or preferably hot or boiling water which denature or inactivate myrosinase. The residue of the sprouts, post-extraction, may or may not be removed from the extract.... The extract can be ingested directly, or can be further treated. It can, for example, be evaporated to yield a dried extracted product. It can be cooled, frozen, or freeze-dried.

Exh. 1-A, col. 11, ll. 18-31. Similarly, the recovery of the “extract” is described at col. 4, ll. 43-45. Each of the 12 examples provided in the specification describe the use of various solvents to “extract” (used as a verb) the desired “extract” (used as a noun) that contains G&I from cruciferous sprouts.

Example 5 describes “extracting ... from:” three day old broccoli sprouts were plunged into boiling water to “extract glucosinolates and isothiocyanates from the plant tissue.” Exh. 1-A, col. 14, l. 62 – col. 15, l. 55. “The sprouts were then either strained from the boiled infusion [tea, soup] or homogenized in it, and the residue then removed by filtration or centrifugation.”

Id.

c. The Prosecution History

The prosecution history supports Caudill's proposed construction. During prosecution of '770 patent application, the applicants explained the scope of the extracting step:

... the method of the present invention involves recovering glucosinolates and isothiocyanates and adding the recovered materials to food....

Amendment and Reply, dated October 22, 2002. Exh. 5-F at 41.

The applicants continued to emphasize that their claims involved removing the desired chemicals (G&I) from the sprouts for further use. *See* Amendment and Reply, dated July 16, 2003, Exh. 5-G at 15-21; *see also* Amendment and Reply, dated Nov. 14, 2005, at 6-7:

"[Claim 10 of the '770 patent] is directed to a method of making a food product that involves adding extracted glucosinolates and isothiocyanates to food." Exh. 5-I at 34-35.

Both glucosinolates and isothiocyanates must be extracted. During prosecution of the '770 patent application, the patent applicants attempted to amend the claims from "glucosinolates and isothiocyanates" to "glucosinolates or isothiocyanates." That request was rejected by the examiner. *See* Amendment, mailed October 9, 2007, Exh. 5-K at 21-26 and Response, mailed October 22, 2007, Exh. 5-K at 31-32. Similarly, in a claim that was initially only directed to glucosinolates, the examiner required the applicants to add "isothiocyanates" to what became issued claim 10. Reply, dated Jan. 20, 2004, at 5. Exh. 5-G at 37. Thus, in the context of the claims "glucosinolates and isothiocyanates" requires the presence of both chemicals.

3. Crucifer; Cruciferous.

"Crucifer" or "cruciferous" means of or related to those sprouts identified and having the characteristics described in the '895 patent specification, at col. 10, l. 28 - col. 11, l. 17.

As outlined above in Section III. B.1.b., throughout the prosecution of the patents-in-suit (and related patents), the patent applicants (particularly named inventor Dr. Paul Talalay) emphasized that their claims were limited to the “designated” or “recited” or “certain” sprouts.

Furthermore, the definition of “food product” requires “sprouts of the instant invention, or extracts or preparations made from these sprouts.” Exh. 1-A, col. 6, ll. 27-29 (emphasis added). The words “of the invention” limit “food product” to the particular sprouts because they “are not descriptions of particular embodiments, but are characterizations directed to the invention as a whole.” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1367 (Fed. Cir. 2007); *Microsoft Corp.*, 357 F.3d at 1348 (The Court found statements in the specification, which repeatedly described a claim term, were not limited to a preferred embodiment, but described the invention as a whole). This language clearly limits the scope of the claims. *Anderson*, 474 F.3d at 1367.

The only “designated” or “recited” sprouts are those specifically listed in the patent specification. They are identified by individual cultivar names. Exh. 1-A, col. 10, ll. 27-65. In addition, the characteristics of “suitable sprouts” are identified: they will have at least 200,000 units per gram of fresh weight of Phase 2 enzyme-producing potential after 3 days of incubation of the seeds and they will be substantially free of indole glucosinolates and their breakdown products. *Id.*, col. 10, l. 66 – col. 11, l. 17.

Reading the patent specification and the prosecution history together, as one must, a person of ordinary skill in the art would conclude that when used in the claims of the patents-in-suit, “crucifer” and “cruciferous” are limited to only those sprouts identified and having the characteristics described in the ‘895 patent specification at col. 10, l. 28 - col. 11, l. 17.

C. Claim Terms To Be Construed

In the context of the patent claims, the patent specification, the prosecution history, and relevant extrinsic evidence as set forth in Caudill's Claim Construction Chart, attached hereto as Exh. AA, the balance of the claim terms having the following meanings:

| Claim Term | Construction |
|---|---|
| Plant tissue | "Plant tissue" is the fresh, soft, fragile plant parts, particularly leaves and stems, capable of being "wounded" by rough handling and so does not include seed. |
| Non-toxic levels of indole glucosinolates and their breakdown products and goitrogenic hydroxybutenyl glucosinolates | The patent does not specify what a non-toxic level of these compounds is and so the term is indefinite. |
| Extracting glucosinolates and isothiocyanates with a non-toxic solvent and isothiocyanates from cruciferous seeds, sprouts, plants or plant parts | <p>"Extracting ... from" means the process of removing glucosinolates and isothiocyanates by a solvent from solid material, <i>i.e.</i>, seeds, sprouts, etc.</p> <p>This claim is ambiguous and capable of two constructions. As such it is indefinite.</p> <p>It can be construed to mean removing both glucosinolates and isothiocyanates from cruciferous seeds, sprouts, plants or plant parts (as those are defined above) using a non-toxic liquid solvent; and removing isothiocyanates from cruciferous seeds, sprouts, plants or plant parts (as those are defined above) using any liquid solvent.</p> <p>Alternatively, it can be construed to mean removing both glucosinolates and isothiocyanates from cruciferous seeds, sprouts, plants or plant parts (as those are defined above) using a liquid mixture of non-toxic solvent and isothiocyanates.</p> |
| Removing the extracted sprouts, seeds, or a combination thereof from said solvent | "Removing the extracted sprouts, seeds, or a combination thereof from said solvent" means that the sprouts, seeds or combination thereof from which the glucosinolates and isothiocyanates have been removed by a solvent are then themselves taken out of the solvent. |
| Recovering the extracted glucosinolates and isothiocyanates | "Recovering the extracted glucosinolates and isothiocyanates" means obtaining the glucosinolates and isothiocyanates that have been removed from the seeds, sprouts, or combination thereof by a solvent from the solvent by further processing such as evaporation, cooling, |

| | |
|--|---|
| | freezing, or freeze-drying. |
| Drying said extracted glucosinolates and isothiocyanates | “Drying said extracted glucosinolates and isothiocyanates” means obtaining the glucosinolates and isothiocyanates that have been removed from the sprouts, seeds, or a combination thereof by a solvent from the solvent by evaporation of the solvent. |
| Said extract is dried, cooled, frozen, or freeze-dried | “Said extract is dried, cooled, frozen, or freeze-dried” means material removed from a crucifer seed or cruciferous sprout by use of a non-toxic solvent, wherein the extract, which can contain the removed material and the solvent, is dried, cooled, frozen, or freeze-dried. |
| Recovering said glucosinolates and isothiocyanates | “Recovering said glucosinolates and isothiocyanates” means obtaining the glucosinolates and isothiocyanates, which have been removed from the seeds or sprouts, from the solvent in which they reside by further processing of the extract, such as evaporation, cooling, freezing, or freeze-drying. |
| At a temperature sufficient to inactivate myrosinase enzyme activity | “At a temperature sufficient to inactivate myrosinase enzyme activity” means at a temperature of at least hot or boiling water. |
| Homogenizing said plant tissue with said non-toxic solvent | “Homogenizing said plant tissue with said non-toxic solvent” means grinding the plant tissue into such small pieces that it is dispersed evenly in the solvent. The plant sample must be completely homogenized, which is not explained in the patent specification and so is indefinite. |

V. CONCLUSION

For all of the reasons set forth above, the terms of the asserted claims should be construed as proposed by Caudill.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2008, the foregoing was filed with the Clerk of the Court via ECF and served in accordance with Southern District's Rules on Electronic Service upon the following parties:

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